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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/390,740	02/17/1995	ROGER COLEMAN		7334

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EXAMINER	
MARSCHEL, ARDIN H	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/390,740	COLEMAN ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40,41,43,44,46-49, 51-56,58-75,80,81,84,85, & 88-110* is/are pending in the application.

4a) Of the above claim(s) *43,44,48,49,51,55,56,58-75,80,81,84,85 and 88-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,41,46,47,52-54, & 105-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) (2 sheets)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) [redacted] (2 sheets)
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 40,41,43,44,46-49,51-56,58-75,80,81,84,85 and 88-110.

DETAILED ACTION

Applicants' arguments, filed 8/5/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

RESTRICTION ISSUES

The restriction requirements as set forth in the Office actions, mailed 12/28/95(original requirement and subsequently elected without traverse), 4/23/01 (constructive election by original presentation and only traversed regarding the practice of *In re Ochiai and In re Brouwer*, which was acknowledged in the Office action, mailed 6/6/02), and 3/3/03 (constructive election by original presentation and argued regarding the practice of *In re Ochiai and In re Brouwer* in applicants' submission, filed 8/5/03, as discussed below), are still deemed proper.

Applicants' argue that the practice of *In re Ochiai and In re Brouwer* should result in the rejoinder of withdrawn polypeptide and antibody claims, in addition to claims to methods of making and using the elected polynucleotides upon indication of allowable subject matter. This argument is partially agreed with and partially disagreed with. It is firstly noted that the original restriction requirement combined certain subject matter claims drawn to polynucleotides as well as hybridization and amplification methods of detection utilizing said polynucleotides. It is agreed under *In re Ochiai and In re Brouwer* that methods of making and using said polynucleotides would be examined

upon indication of claims to allowable subject matter corresponding to claims directed to said polynucleotides. The argument, however, is disagreed with regarding polypeptide and antibody claims. The practice of *In re Ochiai and In re Brouwer* does not extend to including the examination of distinct and/or independent other compositions such as polypeptides and antibodies, or methods of making and using said polypeptides and antibodies, after an indication of allowability of polynucleotides. Polynucleotides are distinct and/or independent from said polypeptides and antibodies. The distinctness and/or independence of polypeptides and antibodies compared to polynucleotides have been set forth in previous statements of restriction requirements.

The above summarized requirements are still deemed proper and are therefore made FINAL.

The claims which are presently under examination are claims 40, 41, 46, 47, 52-54, and 105-110.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The invention as elected via restrictions and/or by original presentation is only directed to PANEC-1 polynucleotides, cells containing them, and methods of use thereof, whereas, in contrast, the present title includes non-elected polypeptides and antibodies.

NEW MATTER

Claims 40, 41, 46, 47, 52-54, and 105-110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been entered via the amending of claim 40 to insert variants directed to a substitution of 1-28 amino acids as compared to SEQ ID NO: 2. Applicants point to the bridging paragraph between pages 6 and 7 of the specification for support. Consideration of said paragraph bridging pages 6 and 7 reveals that replacement of amino acids is described as being guided by comparing homologous cytokines with a particular PANEC and minimizing the number of aa sequence changes in regions of high homology. The above NEW MATTER variant limitation lacks any citation of high homology regions or minimization of the number of aa sequence changes. Applicants additionally compare PANEC-1 to MCP-1 to note 29 aa differences not counting 2 extra amino acids in MCP-1 and concludes that up to 28 substitutions can be made. In response, the disclosure of 29 is clearly different from 28 amino acids thus lacking written basis for the 28 amino acid limitations which is now present in claim 40. Additionally, in response there is no recognition of minimizing changes nor what high homology region is present for sequence changes in MCP-1 as compared to PANEC-1. Also, the comparison to MCP-1 with PANEC-1 is a specific sequence change comparison which does not support the generic 1-28 aa limitation noted above in instant claim 40. Similarly, the 68 aa change limitation in instant claim 107, part b), lacks written basis again as being generic compared to the specific comparison with MCP-1 as filed as well as lacking minimization of changes and high

homology region consideration. Independent claim 52 also contains the above NEW MATTER. This rejection applies to claims which depend directly or indirectly from claims 40 or 52 which also contain the above NEW MATTER due to their dependence. Claim 41 is included also because SEQ ID NO: 1 lacks a complete coding region for the aa sequence of SEQ ID NO: 2 and thus may encode substituted aa which are included in the above NEW MATTER issue.

NEW MATTER has also been entered via the amending of claim 40 to insert the subject matter of variants directed to an insertion or deletion of 1-5 amino acids as compared to SEQ ID NO: 2 wherein specifically the variant has chemokine activity as required in part b), subparts i) and ii) of instant claim 40. Applicants point to support for this 1-5 aa insertion or deletion variant type in the specification on page 7, lines 6-7, wherein such insertions or deletion variants are allowed wherein experimental determination of resulting activity is performed. No such corresponding generic activity determination is present in claim 40. A specific chemokine activity limitation is present in claim 40, part b), subpart ii), but such a specific activity does not have written basis in the specification on page 7, lines 6-7, as pointed to by applicants nor has been found elsewhere. Additionally, it is noted that the 1-5 aa insertion or deletion limitation variant in claim 40 also optionally is claimed wherein no activity limitation is connection thereto at all via the "and/or" limitation in claim 40, line 9. Therefore the 1-5 aa insertion or deletion limitation without any activity evaluation or limitation is also NEW MATTER. This is also NEW MATTER as amended into independent claim 52 as well as

dependent claim 108. This rejection applies to claims dependent directly or indirectly from the above cited claims via their dependence.

Applicants then allege that the cited amino acids in instant claims 105 and 106 are not NEW MATTER due to these being changes which should not be made via comparisons to 3 MCP sequences. In response, the list of amino acids generically not changed in said claim 105 and 106 lack the specificity of the comparison with MCPs as in Figures 3A – 3C contrary to the allegations of applicants on this issue. For example, looking merely at amino acids 1 and 2 of Figure 3A reveals that only the Methionine is invariant where as aa numbers 2-11 all contain variations which is clearly inconsistent with the amino acids listed as 1-2, 4-8, and 10-12 at the beginning of the aa list in claims 105 and 106. This inconsistency between the Figures and instant claims 105 and 106 continues throughout the Figures 3A – 3C sequence comparisons thus documenting the NEW MATTER in these claims regarding the selection of amino acids to be kept invariant compared to SEQ ID NO: 2 as in claims 105 and 106.

NEW MATTER has also been amended into the claims via the limitation "non-genomic" in claims 107, parts a) – d), which has only been pointed to by applicants regarding written support as filed as noted below and no other support has been found via consideration of the entirety of the instant disclosure as filed. Applicants point to the specification as filed on page 10, lines 23-25, for support for nongenomic limitations in claim 107. Consideration of said page 10 citation reveals that it is directed to probe derivations from all of the common parts of a genomic sequence, such as promoters, enhancer elements, etc. which is deemed inclusive of overlapping region probes and

which lacks any recognition as to what is meant by non-genomic and thus fails to support the non-genomic limitation in instant claim 107.

NEW MATTER IN SEQUENCE LISTING

The amendment, filed 7/25/01, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

SEQ ID NO: 1 in the 7/25/01 filed sequence listing only contains 289 nucleotides whereas the corresponding sequence as filed in Figure 1 has 291 nucleotides. This shortened sequence is therefore NEW MATTER.

Applicant is required to cancel the new matter in the reply to this Office Action.

SEQUENCE RULE NON-COMPLIANCE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statements under 37 CFR §§ 1.821(f) and (g), regarding the originally filed SEQ ID NO: 1 in Figure 1, as filed. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and

computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

LACK OF WRITTEN DESCRIPTION

Claims 40, 41, 46, 47, 52-54, and 105-110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is reiterated and maintained from the previous office action, mailed 3/3/03, regarding the lack of written description basis for the rejection and explained further as being relaxed as follows. Regarding PANEC-1 polynucleotides, the only sequences which have written description are those of SEQ ID NO: 1 or the sequences which encode SEQ ID NO: 2 via the well known optionally redundant amino acid triplex nucleic acid codons as are present in mature mRNA or the equivalent cDNA. It is noted that a variety of variant, recombinant, mutant, and fragment sequences, however, are also encompassed by the instant claims. The sequences of such variants etc. have not been provided to support the numerous variant embodiments other than those sequences summarized above in this paragraph. In particular, the written description of variant sequences or fragments which retain chemokine or other desired and/or related activities have not been provided as filed. The disclosure of the presumed presence of

such variant or fragment sequences does not disclose what specific sequences meet any of the variant characteristics as presently claimed.

Applicants first focus on and argue that there is no intention to include "full gene" embodiments within the instantly claimed subject matter and that there has been no express intent to include genomic sequences in the instantly claimed subject matter. In response, a vast plethora of genes in a wide variety of genomes of organisms are known and described in the art as encoding a proteins, for example. It is not seen, nor has a definition been pointed to, by applicants wherein the encoding wording regarding polynucleotides defined thereby as present in the instant claims is limited to being limited to cDNA which has been prepared from mature mRNA. Applicants attempt to add a definition of what is meant by encoding after filing does not negate the far broader concept of encoding that is present in the art and reasonably interpreted regarding the meaning of encoding limitations in the instant claims as also originally filed. It is noted, however, that notwithstanding the above arguments and response, the only written description for polynucleotides is via a sequence is directed to SEQ ID NO: 1 or the above described encoding via well known and art recognized codon practice. No intron vs. exon disclosure(s) have been instantly set forth which again supports the lack of written description of such broadly included sequences. It is additionally noted that the vast number of variant sequences and/or fragments thereof also are included as lacking written description under this rejection and that claims containing these added variants as subject matter are rejected as lacking written description.

Applicants then point to the legal decision of the Federal Circuit regarding the construing of claims which supports the avoidance of definitions which were not examined by the PTO. In response the fact pattern of this legal decision is different from that of this application prosecution. In the instant application the construing of claim interpretation has clearly been considered and examined at the PTO contrary to the concern regarding non-PTO examined definitions as in the legal decision. Therefore, the legal decision is moot regarding this rejection. Applicants then argue that no support is present in the specification for a torturous claim construction. In response claims and specification disclosures are to be interpreted as broadly as reasonable with also recognizing well known art definitions. Thus, the encoding of proteins by either a genomic sequence as well as mature mRNA and equivalent cDNA is deemed included in the interpretation of the instant claims thus leaving the lack of written description of genomic sequences which may include introns, for example, as not having written basis as filed thus supporting this rejection. Applicants point to the specification as filed on page 10, lines 23-25, for support for nongenomic limitations in claim 107. Consideration of said page 10 citation reveals that it is directed to probe derivations from all of the common parts of a genomic sequence, such as promoters, enhancer elements, etc. which lacks any recognition as to what is meant by nongenomic and thus fails to support the nongenomic limitation in instant claim 107.

VAGUENESS AND INDEFINITENESS

Claims 40, 41, 46, 47, 53, 54, and 105-109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 40, part d), the word "specifically" is present to characterize antibody binding. This limitation has not been defined in the specification and may conflictingly be interpreted regarding its metes and bounds. Does it intend to mean that specificity is to distinguish all other polypeptides from SEQ ID NO: 2? Does the specificity mean that SEQ ID NO: 2 can be thereby distinguished from what applicants describe as the closest relative, that of MCP-1? Claims 107 and 108 also explicitly contain this unclarity. Similarly, claims 53 and 54 cite the phrase "specifically hybridizes" which are equivalently vague and indefinite as to what specificity is meant. Clarification via clearer claim wording is requested. Claims which depend from claim 40 are also included herein due to their dependence.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 46, 47, 52, 53, and 107-100 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yoshimura et al. [FEBS Lett. 244(2):487 (1989)].

Yoshimura discloses the cDNA cloning of MCP-1 as summarized in the title and abstract. The MATERIALS AND METHODS section on pages 488 and 489 of the reference disclose the details of cloning and sequencing of MCP-1 coding sequence which is then given as results in Figure 2 on page 488 and Figure 7 on page 491. The cloned cDNA (also therefore claims 46 and 47) anticipates the cytokine active fragment limitations contained in a polynucleotide as required by instant claim 40. Applicants have also argued that MCP-1 contains cytokine active fragments in their REMARKS, filed 8/5/03. Part b) of instant claim 40 is anticipated because the reference sets forth a recombinant (cloned, that is) variant as in said part b). The variant as chemokine activity as required in part b). The variant has a substitution of at least 1-28 amino acids compared to instant SEQ ID NO: 2 as verified in instant Figures 3A – 3C. The open claim wording term "has" in instant claim 40, part b), subparts i) and ii), is reasonably interpreted to include sequence substitutions, insertions, or deletions of more than 1-5 amino acids or 1-28 amino acids thus supporting this rejection. The "comprising" open claim wording in instant claim 52, line 1, also results in instant claim 52 being anticipated for the equivalent reasons as above. Additionally, the cloned polynucleotide in the reference anticipates part c) of instant claim 40, as well as parts c), g), and i) of instant claim 107, because polynucleotide encodes a biologically active fragment with chemokine activity of SEQ ID NO: 2 as required therein which again is further verified by the sequence comparison of instant Figures 3A – 3C. The cloned cDNA of the reference includes complementary sequences due to being double stranded thus also anticipating parts f) and g) of instant claim 40. The cDNA is disclosed in the reference

in the above cited sections as being prepared from mRNA thus also supporting the rejection of part i) of instant claim 40. The use of hybridization probes for isolation of polynucleotides of the reference is described in Figure 1 on page 488 and associated explanations thus also anticipating the methods of instant claim 53. Instant claims 108-110 also contain the above limitations which results in these claims also being anticipated by the reference.

POSSIBLE INTERFERENCE PROCEEDINGS

Applicants have provided arguments direct to the Luster et al. document (U.S. Patent 6,403,782) regarding possible interference proceedings. This issue will be considered after there is at least one allowable instant claim indicated which also hopefully will clarify whether a two-way test is met regarding possible interfering subject matter.

INFORMATION DISCLOSURE STATEMENT

Applicants requested clarification as to any references cited on Forms PTO 1449 that might to resubmitted due to a lack of publication date(s). By way of clarification, reconsideration of previously executed Forms 1449 have revealed only one such lined through citation which is directed to U. S. Patent Application Serial Number 08/294,251. Resubmission of this document is not required as it is hereby indicated as having been considered as being available at the PTO. The PTO now does permit the citation of such applications on a PTO Form 1449 and it is cited on the enclosed PTO Form 892 to make it of record on such a document.

A re-executed PTO Form 1449, filed 2/17/95, is enclosed to include the initialing of document AR which apparently was inadvertently not previously initialed on said PTO Form 1449.

A copy of a corrected PTO Form 892, originally executed on 12/17/95, is also included herewith to line through a document citation which was supplied without a date of publication regarding a non-Patent document.

INFORMALITIES

The disclosure is objected to because of the following informalities:

The Drawings contains parts indicated as FIGURES 2A, 2B, 3A, 3B, and 3C. In contrast the specification at pages 5 and 6 in the section entitled "DESCRIPTION OF THE FIGURES" lacks a separate brief description of said FIGURE parts as required.

In the specification on page 17, line 14, Figure 3 is cited which conflicts with the present Figure designations. There is no longer a Figure 3 per se, but rather Figures 3A – 3C.

The capitalization of the PANEC-1 and PANEC-2 designations confusingly vary in the specification such that panec-1 and panec-2 are also cited. Such differences in citation may confuse whether the same materials are meant for differently capitalized designations or not. See, for example, the specification on page 17, lines 10-17.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices

published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 21, 2003

Ardin H. Marschel